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July 26, 2019

Susan H. Newton RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Sections
410 Capital Avenue
P.O. Box 340308
Hartford, CT 06134-0308

RE: Lawrence + Memorial Hospital, Letter of Violation, dated July 16, 2019.

Dear Ms. Newton,

Attached is Lawrence + Memorial Hospital's response to the Department of Public Health letter dated July 16, 2019 containing plans of correction and responses for the violations set forth in the letter.

Please confirm receipt of the corrective action plans and their acceptance status.

If you need additional information, please contact me at Victoria.DahlVickers@ynhh.org or by phone at (203) 688-6374.

Sincerely,



Victoria Dahl Vickers RN, MBA
Executive Director Accreditation & Regulatory Affairs
Clinic Building, 1st Floor, Room CB1049J
Yale New Haven Health
20 York Street
New Haven, CT 06510

VDV:jd:attachment

CC: Steven Choi
Patrick Green
Denise Fiore
Oliver Mayorga, MD

FACILITY: Lawrence & Memorial Hospital

DATES OF VISIT: December 10, 11, 12, 17, 18, 19, 20, 2018, January 7, 31, March 21 and May 10, 2019

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a)
Physical plant (1) and/or (b) Administration (2) and/or (i) General (b).

1. *Based on a tour of the hospital and review of hospital documents the hospital failed to ensure that patient's on the Behavioral Health Unit were cared for in a safe setting that was free from ligature points and other safety hazards which had been previously identified by the hospital. The findings include:

On 12/11/18 at 10:00 AM, during a tour of the Behavioral Health Unit, while accompanied by the Behavioral Health Unit Director and the Director of Engineering the following was observed:

- a. The electrical receptacles throughout the Behavioral Health Unit (Pond 4) to include resident rooms were not designed to a psychiatric institutional standard i.e. not tamper resistant and/or not controlled by staff.
- b. The doors to rooms throughout the Behavioral Health Unit (Pond 4) had hinges and door handles that posed a potential hanging hazard and were not designed to a psychiatric institutional standard.
- c. There were open wall HVAC registers & grilles on the unit that posed a potential hanging hazard and were not designed to a psychiatric institutional standard.
- d. The bathroom 7-908 had a lock & hasp on the box that covered the handicap shower that is not designated for use by behavioral patients and posed a potential hanging hazard. The nurse call box for this room and room 7-924 could be pulled away from the wall posing a potential hanging hazard and not designed to a psychiatric institutional standard.
- e. The observation room had a plate glass window for staff to observe patients that is easily breakable and not designed to a psychiatric institutional standard posing a hazard to staff and patients.
- f. That the patient bathrooms and shower rooms throughout the unit were not provided with soap dispensers that are listed and approved as "institutional" in construction and are deemed not appropriate for use in the environment in which they are installed; i.e. commercial-style, plastic-resin type dispensers can injure patients or others if misused.
- g. The patient bathrooms and shower rooms throughout the unit had grab rails the were not tight to the wall and had gaps that posed a potential hanging hazard.

The hospital conducted an environmental risk assessment in 9/2018 which identified the above noted ligature points. The hospital identified that many items needed to reduce ligature risks such as door hinges were on back order. Prior to this inspection, the hospital had no date for abatement of these hazards.

In addition, although the hospital identified that environmental hazards existed on the Behavioral Health Unit, no additional safety measures were implemented to ensure patient safety while awaiting abatement of the environmental hazards.

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An immediate action plan was requested and included current patient risk assessments and the addition of environmental safety rounds.

The patient census was 15. There were no patients with current suicidal or self-harm tendencies.

1 DPH Plan of Correction: Ligature Risk	Completion Date
<ul style="list-style-type: none">• A Safe Environment Checklist was created.• An every 15 minute Safe Environment check utilizing the Safe Environment Checklist for Lawerence + Memorial (L+M) Pond 4 unit was implemented on 12/11/18 and did remain in place until Ligature risk remediation was completed.	12/11/2018 5/17/2019
Monitoring Plan <ul style="list-style-type: none">• 10 Safe Environment Checklists were audited weekly until ligature risk remediation completion.	5/17/2019
Continued Plan <ul style="list-style-type: none">• Education has been provided to regularly scheduled L+M Pond 4 Registered Nurses, Health Unit Coordinators, and Mental Health Councilors regarding the Safe Environment Checklist, the Standing Operating Procedure, and the GMI Ligature Risk Assessment.• Associates from outside L+M Pond 4 who conducted the Safe Environment Checklist were educated regarding the Safe Environment Checklist, the SOP, and the GMI Ligature Risk Assessment.• L+M Psychiatry Providers on-site were educated regarding the Ligature Risks within the Pond 4 environment, the need for every 15 minute Environmental safety checks, and conducting a baseline suicidality assessment on 12/11/18.• A Lawrence and Memorial (L+M) Psychiatry Provider re-assessed each patient that L+M Pond 4 unit during the day shift of 12/11/2018 for suicidality.	1/11/2019 2/8/2019 12/11/2018 12/11/2018
Monitoring Plan <ul style="list-style-type: none">• On 12/11/18 an L+M Psychiatry Provider completed an audit of current Pond 4 patient's medical records to assess that each Pond 4 patient received a suicidality assessment on 12/11/2018.	12/11/2018
Continued Plan <ul style="list-style-type: none">• Patients on L+M Pond 4 are assessed for suicidality by a Registered Nurse every shift.	Ongoing
Monitoring Plan <ul style="list-style-type: none">• 10 Suicide Assessments performed by Registered Nurses were audited weekly for two months.	2/9/2019

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Continued Plan <ul style="list-style-type: none">• Remediation of Ligature Risks within L+M Pond 4 as identified within the CT DPH survey and the GMI Ligature Risk Assessment of L+M Pond 4 was completed. <p>The Director of Psychiatric Services was responsible for Plan of Correction oversight.</p>	5/17/2019
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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical plant (1) and/or (b) Administration (2) and/or (g) Pharmacy (3) and/or (i) General (b).

2. *Based on documentation review, tour of the hospital pharmacy and compounding areas and staff interviews, the hospital failed to ensure that the hospital pharmacy was in compliance with the USP 797 standard for compounding of medication to ensure the safety and well-being of patients. The following was observed:
- a. On 12/11/18 at approximately 11:12 AM, the ceiling tile in the Biological Safety Cabinet Room (Chemo Prep and Compounding Room) was lifted away from the ceiling grid due caulking that separated from the ceiling grid and tile, failing to maintain the separation from the ceiling cavity above.
 - b. Caulking was separating from the ceiling grid in multiple areas, however the ceiling envelope was secure in the in the laminar air flow workbench area and anti-room. Interview of the Lead IV room tech indicated the rooms had just been recertified for use and she didn't know when engineering had last conducted ongoing maintenance inspections to identify areas or equipment in need of repair.

Subsequent to these observations, the hospital developed an action plan that included recommendations from consultation with the Department of Consumer Protection Drug Control Section. Aspects of the plan included reducing the IV compounding production to only low risk medications with a 12 hour Beyond Use Date (BUD), moving medium risk compounding to an off-site facility, repair of caulking, terminal cleaning and recertification.

2 DPH Plan of Correction: IV Clean Room	Completion Date
• Compounding at the Lawrence and Memorial Hospital (L+M) main campus was limited to low risk compounding with maximum 12 hour Beyond Use Date (BUDs).	12/29/2018
• Low risk medications were admixed as close to scheduled administration times as possible.	12/29/2018
• Medium risk compounds and all batch compounding were compounded at Smilow Cancer Hospital, Waterford (included under the L+M license as a satellite location).	12/29/2018
• Epidural cassette compounding was completed at Smilow Cancer Hospital,	12/29/2018

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Waterford with approval by the CT DEA field office.	
• Appropriate refrigerated storage was maintained during transportation.	12/29/2018
• Education was sent via e-mail to pharmacy staff responsible for compounding at LMH regarding compounding restrictions indicated above.	12/11/2018
• Signage was placed throughout the L+M IV room for reinforcement.	12/11/2018
• Education regarding the maximum 12 hour beyond use dates was disseminated to clinical staff via e-mail.	12/11/2018
• Sealant to the ceiling tile was applied to close gaps.	12/13/2018
• Terminal cleaning occurred after product curing of 24 hours.	12/14/2018
• Recertification was completed.	12/24/2018
• Final report of passing viable sampling was received.	12/29/2018
• L+M main campus IV clean room returned to normal compounding operations following receipt of DCP and DPH permission.	
• Pharmacy, infection prevention, and facilities/engineering leadership initiated and currently participate in monthly rounds of the IV room spaces. All rooms are visually inspected from the perspectives of one's expertise and any concerns are identified/resolved in real-time. Results are discussed at the USP 797 Committee.	1/22/2019
Monitoring Plan	
• Infection Prevention (IP) monitored for any increase in invasive infection related to mold on a weekly basis and until the clean room was recertified. Unusual activity was to be reported to the IP committee and IP Chair if indicated. None indicated.	12/24/2019
The Director of Pharmacy was responsible for overseeing the completion and monitoring of the Plan of Correction.	

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (d) Medical Records (1) and/or (i) General (b).

3. *Based on a review of clinical records and staff interview, for one of twelve (12) patients reviewed for antiseizure medication (Patient #33) the hospital failed to ensure that numerous medical staff that assumed the care of the patient, effectively managed the patient's critical medication during hospitalization. The finding includes:
 - a. Patient #33 was admitted to the Emergency Department (ED) on 3/18/17 for increased lethargy. The admission history and physical dated 3/18/17 identified the patient had a history of seizure disorder and was receiving Depakote Sprinkles 50 0mg twice a day prior to admission. A physician History and Physical note dated 3/18/17 identified Patient #33 had an altered mental status/possible Urinary Tract Infection (UTI) and was started on Intravenous (IV)

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antibiotics and IV hydration. Review of admission laboratory blood work dated 3/18/17 identified Patient #33's Valproic acid (Depakote) level was 65 (norm 50-100ug/mL). Patient #33 was admitted for in-patient care from 3/19/17 until discharge on 3/28/17.

Review of Patient #33's medication administration record dated from 3/18/17 to 3/28/17 identified that the patient did not receive any Depakote or similar anti-seizure medication during the 10 day hospitalization.

Review of Patient #33's clinical record dated from 3/19/17 to 3/28/17 identified that no additional Valproic acid blood levels were requested or drawn.

Review of the clinical record identified that Patient #33 was under the care of 3 or more physicians and/or Advanced Practice Registered Nurses (APRN) from 3/19/17 to 3/28/17.

Review of Patient # 33's discharge paperwork dated 3/28/17 identified Patient #33's discharge medications included Depakote Sprinkles 500mg twice a day.

Interview with MD #7 on 1/10/19 at 8:50AM stated when Patient #33 was admitted to the ED, he/she had an altered mental status and he felt it was not safe for the patient to take anything by mouth. MD #7 held Patient #33's medications, including the Depakote Sprinkles on the night of 3/18/17. MD #7 further stated that he did not document in the clinical record that he held Patient #33's Depakote Sprinkles and was not involved in Patient #33's care after being admitted for in-patient care.

Interview with MD #8 on 1/15/19 at 11:30AM stated she assessed Patient #33 on 3/19/17 and 3/20/17. MD #8 stated she reviewed the patient's history including medications the patient was taking prior to the hospital admission. MD #8 stated that when she assessed the patient, the patient was somnolent so she held the seizure medication (Depakote). MD #8 identified that she did not document in the clinical record that the Depakote continued to be held or why no Depakote level was ordered. MD #8 was not involved in Patient #33's care after 3/20/17.

Interview with MD #10 on 1/28/19 at 11:30 AM identified that he cared for Patient #33 on 3/21/17. MD #10 reviewed Patient #33's medications, knew the patient's anti-seizure medication was on hold, and continued to hold the medication due to continued altered mental status. MD #10 did not document in the clinical record that the Depakote continued to be held. MD #10 was not involved in the patient's care after 3/21/17.

Interview with MD #9 on 1/28/19 at 10:45 AM stated that he took care of Patient #33 on 3/22/17 and 3/23/17. MD #9 reviewed Patient #33's history prior to admission including the

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patient's medications. MD #9 stated that she was focused on Patient #33's active issues of pneumonia and hypertension and did not have any recollection of the patient being on Depakote. MD #9 further stated that she did not know why the patient was not started back on Depakote Sprinkles when the patient's health continued to improve. MD #9 was not involved in the patient's care after 3/23/17.

Review of Patient #33's clinical record between 3/24/17 and 3/2/17 identified Patient #33 was seen by multiple practitioners who were unavailable for interview.

Interview with MD #11 on 1/7/19 at 2:00 PM stated that he took care of Patient #33 on 3/28/17, the day of discharge. MD #11 reviewed Patient #33's home medication and included the Depakote on the discharge paperwork. MD #11 was not aware that Patient #33 did not receive Depakote during admission.

Patient #33 was readmitted to the hospital ED on 3/28/17 at 8:35 PM. Review of the ED admission documentation identified Patient #33 arrived with prolonged seizure activity (status epilepticus) and arrived actively seizing as the paramedic was medicating the patient with a second dose of Versed. Patient #33 was then assessed as postictal (altered state of consciousness after an epileptic seizure). The clinical record identified that Patient #33 was discharged today (3/28/17) from the hospital and now was re-admitted for prolonged seizure activity lasting approximately 10 minutes. Patient #33 arrived unresponsive to painful or verbal stimuli. Documentation identified that Patient #33 was supposed to be on Depakote Sprinkles but the Valproic acid level was less than therapeutic at this time. Review of the Valproic acid level dated 3/28/17 at 9:37 PM identified the level was 3 (norm 50-100 ug/mL).

While in the ED, Patient #33 was treated with multiple medications including Versed on admission. An ED observation note dated 3/29/17 identified that at 1:20 AM Patient #33 was noted to have recurrent seizure activity. Blood gases were drawn that showed significant acute respiratory acidosis. Patient #33 was intubated related to the blood gas levels and the need for sedation to treat the seizures. Despite treatment efforts, Patient #33 was placed on comfort care and expired on 4/11/17.

Interview with the Accreditation Regulatory Specialist on 12/17/18 at 1:45 PM and review of Pt #33's clinical record identified that although Pt #33's admission paperwork dated 3/18/17 identified the patient was on Depakote Sprinkles 500mg twice a day, the clinical record lacked any documentation of why the patient did not receive the seizure medication during the 10 day admission. The Accreditation Regulatory Specialist stated she spoke to a pharmacist who confirmed that no anti-seizure medications were ordered for Patient #33 and that Patient #33 did not receive anti-seizure medication while hospitalized from 3/17/17 through 3/28/17.

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Interview with the Chief Medical Officer on 1/31/19 at 12:30 PM identified that prior to this investigation of Patient #33's medical care, the hospital did not have a policy or formalized process to ensure that home medications placed on hold were communicated between practitioners. Subsequent to investigator inquiry, the medical staff enhanced their practitioner to practitioner hand-off of a patient's care to include critical medication status if a medication is placed on hold. In addition, the hospital will be enhancing the computerized medical record to identify critical medications that are on hold or other critical medication information necessary for practitioner to practitioner hand-off of a patient's care.

3 DPH Plan of Correction: Medical Management	Completion Date
<ul style="list-style-type: none">The Emergency Room Pharmacy Medication Reconciliation process was enhanced in the L+M Healthcare Pharmacist Responsibility Grid. The enhancement included: Patients that were on anti-epileptic(s) medication prior-to-admission, the pharmacist completing admission medication history/reconciliation verbally clarified with the covering provider whether the home anti-epileptic(s) medications were to be being held on admission intentionally. This clarification is now documented as part of the admission medication reconciliation process.	2/28/2019
<ul style="list-style-type: none">Education for Pharmacy staff involved in the medication reconciliation process began on February 15, 2019.	4/30/2019
<ul style="list-style-type: none">Hospitalist providers standardized the admission History and Physical/medication reconciliation documentation as the means of communicating medications on hold.	4/30/2019
<ul style="list-style-type: none">Standardization was achieved by utilizing a provider template or an electronic smart phrase available in the Epic Smart Phrase Manager system.	3/6/2019
<ul style="list-style-type: none">Education for hospitalist providers began on February 20, 2019.	3/6/2019
<ul style="list-style-type: none">An article for review was provided to the hospitalist staff :<ul style="list-style-type: none">Schater, Steven. "Anti-seizure drug: Mechanism of action, pharmacology and adverse effects." www.uptodate.com Dec 21, 2018	3/6/2019
<ul style="list-style-type: none">Pharmacy staff provided the Hospitalists an in-service education focusing on: Common anti-seizure medications, conversion from PO to IV dosage of common anti- seizure medication and the monitoring of blood level values for therapeutic goals.	4/30/2019
Monitoring Plan <ul style="list-style-type: none">Pharmacy leadership tracked and reviewed data related to anti-epileptic medication provider order clarifications for 2 months.The Chairman of the Department of Medicine or designee monitored 30 patient records per month x 2 months for compliance with the use of the standard communication and documentation. Beginning: 3/1/2019	3/6/2019
The Chairman of Medicine was ultimately responsible for the completion and monitoring of the Plan of Correction.	4/30/2019

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4. Based on clinical record review and interviews for 1 (P #41) of 3 patients who underwent a surgical procedure the facility failed to ensure that the patients' care was coordinated preoperatively. The findings include:

a. Patient (P) #41 with diagnoses that included developmental and cognitive deficits, was admitted to the hospital on 4/6/18 for an elective surgical procedure. According to medical record documentation P#41 arrived at the facility at 12:21 PM, was prepared in the preoperative area and was ready for the procedure as scheduled at 2:16 PM. Medical record documentation indicated the patient had not received anesthesia until 4/6/18 at 8:30 pm and the anesthesia ended at 9:55 PM. Review of the medical record failed to identify that P#41 and/or his/her Power of Attorney (POA) was promptly notified of the delay in surgery and/or the option to leave the facility and reschedule the procedure.

During an interview with the Manager of Patient Relations on 1/3/19 at 9:30 AM he/she indicated due to the extensive delay Person #10 had not asked for options and/or been provided options such as leaving and rescheduling the elective procedure. As a result of the identified concern several changes have been made such as staff offering the patients the option of leaving and rescheduling and when making out the OR schedule a patients special health care needs will be taken into consideration when scheduling the procedure.

Hospital Patient Rights and Responsibilities policy indicated the patient/patient representative has the right to considerate and respectful care. In addition the policy indicated the hospital, within its capacity, recognizes and responds to individual needs, disabilities and preferences.

4 DPH Plan of Correction: Delay in OR schedule and Patient Rights	Completion Date
• A unit based safety huddle dialogue was initiated regarding the importance of documenting safety rounds on patients, specifically those who are in the situation of an unintended delay in Operating Room (OR) scheduling.	5/22/2018
• Staff were educated on the specific location of where to document safety round for the Ambulatory Surgical Unit (ASU)/ Same Day Surgery (SDS) in the Electronic Medical Records (EMR).	5/22/2018
• Staff were re-educated on the concern that if there is a substantial delay, the staff is to document the conversation with the patient and make a notation regarding rounds under the Safety section in the EMR.	5/29/2018
• Organizational Leadership is fully committed to diversity and inclusion within our healthcare community.	1/31/2019
• A monthly Diversity and Inclusion Committee was established in January 2019 to educate staff within the organization on the importance of diversity and inclusion and its relation to the culture and competency of healthcare.	1/31/2019
• A Diversity and Inclusion orientation segment was initiated for all new	

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employees within our organization.	1/31/2019
<ul style="list-style-type: none">A dialogue with the Management Council was initiated May 2019 to offer leadership the opportunity to share their patient and staff experiences, discuss issue resolution and improvement topics.	5/31/2019
<ul style="list-style-type: none">A task force was created to present the importance of diversity and inclusion and how it supports our Vision, Mission and Values statement in our organizations.	7/22/2019
Monitoring Plan <ul style="list-style-type: none">The Manager of ASU or designee will audit 10 records a month, or all files less than 10, for 2 months of patients who have had a greater than 3 hour delay in scheduled case time for compliance with safety rounding documentation.	10/1/2019
The Manager of ASU is responsible for the oversight of the Plan of Correction.	

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1).

5. Based on observation and observation of the Emergency Department (ED) crisis unit for 1 of 2 patients on video monitor (Patient #13) the hospital failed to ensure patient privacy. The findings include:

- a. Patient #13 was admitted on 12/10/18 with suicidal ideations and placed in a monitored bed.

Observation on 12/10/18 at 10:00 AM identified that a monitor screen was present at the staff desk and was visible from the hallway which was accessible to other patients. The monitor screen identified Patient #13 lying in bed wearing hospital clothing without protection of privacy. Subsequent to surveyor inquiry, the monitor screen was repositioned and no longer visible to the hallway.

5 DPH Plan of Correction: Patient Privacy in ER	Completion Date
<ul style="list-style-type: none">A privacy screen was ordered and applied to the monitor screen in the Crisis Intervention Unit.	1/31/2019
<ul style="list-style-type: none">Emergency Department Registered Nurses (RNs), Technicians, and Patient Care Attendants are being reminded of patient's privacy and the need to ensure the monitor screen is not visible to patients or visitors via Safety Huddle.	7/31/2019
Monitoring Plan <ul style="list-style-type: none">The Emergency Department Leadership will audit ten observations of the monitor screen position per month for two months to determine if the screens are not viewable by patients and visitors and that the privacy screen is intact.	9/30/2019
The Director of Emergency Services is responsible for the implementation and completion of the plan of correction.	

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6. *Based on clinical record review, review of hospital policies and interviews for 5 of 6 patients placed on observational status (Patients #61, #62, #63, #28 and #11) the hospital failed to ensure that patients with an appointed conservator of person and/or patients with cognitive impairment did not sign a legal document (Medicare Outpatient Observation Notice). The findings include:
 - a. Patient #61 was admitted to the Emergency Department (ED) on 11/8/17 and had a past medical history of intracranial injury. A physician order directed Patient #61 be placed on observational status. Despite an interagency patient referral report (W10) that identified Patient #61 had an Attorney appointed as the responsible person, hospital registration staff had Patient #61 sign a Medicare Outpatient Observation Notice. The signing of this notice identified that it had or had the potential to financially impact the patient's financial responsibilities on admission or return to a skilled nursing facility.
The hospital's policy for Observational Reviews identified that if the patient is unable to sign the letter of observation notice, the responsible party will be notified. The conversation with the responsible party is noted on the letter documenting who was notified, date, time and signature.
Interview with Utilization Management RN #30 and the Director of Patient Access on 2/1/18 at 1:00 PM identified that patients who are conserved or have a responsible person identified on the W10 should not sign or ask to sign a Medicare Outpatient Observation Notice.
 - b. Patient #62 was admitted to the ED on 10/22/18 with increased lethargy. A physician order directed Patient #62 be placed on observational status. Despite an interagency patient referral report (W10) that identified Patient #62 had a Conservator of Person, hospital registration staff had Patient #62 sign a Medicare Outpatient Observation Notice. Interview with Utilization Management RN #30 and the Director of Patient Access on 2/1/18 at 1:00 PM identified Patient #62 not have been asked to sign the Medicare Outpatient Observation Notice.
 - c. Patient #63 was admitted to the ED on 11/2/18 with complaints of chest pain with deep breathing. A physician order directed Patient #63 be placed on observational status. Despite the interagency patient referral report (W10) that identified Patient #63 had a responsible person identified, hospital registration staff had Patient #63 sign a Medicare Outpatient Observation Notice. Patient #63 was admitted to the ED a second time on 11/29/18. A physician order directed Patient #63 be placed on observational status. Despite an interagency patient referral report (W10) that identified Patient #63 had a Conservator of Person (same person as listed as responsible person on 11/2/18), hospital registration staff had Patient #63 sign a Medicare Outpatient Observation Notice. Interview with Utilization Management RN #30 and the Director of Patient Access on 2/1/18 at 1:00 PM identified Patient #63 should not have been asked to sign the Medicare Outpatient Observation Notice on 11/2/18 or 11/29/19.
 - d. Patient #28 was admitted to the ED on 6/14/18 with a diagnosis of dementia with behavioral disturbances. A physician order directed Patient #61 be placed on observational status. Review of an initial psychiatric evaluation on 6/14/18 identified that Patient #28 had an appointed conservator. Despite the patient's altered mental status and identified

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conservator, hospital registration staff had Patient #28 sign a Medicare Outpatient Observation Notice. Interview with Utilization Management RN #30 and the Director of Patient Access on 2/1/18 at 1:00 PM identified Patient #28 should not have been asked to sign a Medicare Outpatient Observation Notice.

- e. Patient #11 was admitted to the ED on 11/11/18. An ED evaluation dated 11/11/18 identified that Patient #11 did not have the capacity to make his/her own medical decisions and was gravely disabled by virtue of cognitive impairment. A physician order directed Patient #11 be placed on observational status. Despite the patient being identified as gravely disabled by virtue of cognitive impairment, hospital registration staff had Patient #11 sign a Medicare Outpatient Observation Notice. Interview with Utilization Management RN #30 on 2/1/18 at 1:00 PM identified that any patient who was cognitively impaired should not have been asked to sign a Medicare Outpatient Observation Notice.

6 DPH Plan of Correction: MOON signed by conserved patients	Completion Date
• The process of filing clinically relevant documents was reviewed by Health Information Management (HIM). It was determined that there was from the previous process of electronically filing the relevant forms after discharge was an opportunity for improvement.	2/28/2019
• The process was revised to follow Health Information and Management Systems Society (HIMSS) Stage 7 Recognition, a certification that represents successful implementation of clinically relevant document imaging upon admission. This allows the hospital to no longer be dependent on paper documents to deliver and manage patient care.	2/25/2019
• Training was completed on the scanning of clinically relevant documents into the EMR. This was provided to Health Unit Coordinators (HUCs) of the inpatient units and Emergency Room during the month of March and April 2019 by HIM management.	4/8/2019
• Education to the providers regarding the location of scanned documents and how to access the clinically relevant documents was provided via e-mail message.	5/3/2019
• HIM manager attended Patient Care Services Leadership and Health Unit Clerk staff meetings to reinforce and seek support of the HIMSS 7 initiative.	5/21/2019
• HIM leadership initiated rounding to ensure timely processing and appropriate management of documents.	3/31/2019
Monitoring Plan <ul style="list-style-type: none">HIM team will perform 100% quality check of HUC-indexed documents to ensure timely scanning and accurate placement of clinically relevant documents x 2 months.	10/1/2019
The manager of HIM is responsible for the oversight of this section.	
Patient Access <ul style="list-style-type: none">The Medicare Outpatient Observation Notification (MOON) Procedure was updated by Patient Access Leadership.Emergency Room (ER) Registration Staff were retrained on the new procedure	6/30/2019
	6/30/2019

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<p>for the administration of the MOON.</p> <ul style="list-style-type: none">• <u>The updated process:</u> The Arrival Registrar will review the “Responsible Party” section of the W-10 Interagency form on all patients transferred from other facilities (e.g. SNFs), update the Patient Contact section of registration as needed when a legal representative (e.g. conservator) is listed on the W-10, and immediately scan the document into EMR if not already done so by the ED HUC.• <u>Continued updated process:</u> At some point after the patient is fully triaged, the ED registrar will contact the patient’s conservator to update patient demographics, insurance information and to explain and get consent for all applicable regulatory forms. Account notes will be entered concerning all attempted/actual conversations with the conservator.• A multidisciplinary process improvement task force will assess the process of how advance directives are identified and communicated throughout the care continuum. A scoping kick-off session has been scheduled for August 28, 2019 and subsequent meetings will focus on improving identification/communication. Target completion date is the end of November, 2019.	7/22/2019
<p>Monitoring Plan</p> <ul style="list-style-type: none">• Random shadowing of 2 ED registration staff members who administer the MOON will be completed weekly for 2 months for compliance with the scanning of the MOON and documentation of the communication with the conservator.	7/22/2019
<p>The Manager of Patient Access is responsible for the oversight of this section.</p>	11/30/2019
<p>Care Management</p> <ul style="list-style-type: none">• Care Management staff were re-educated regarding the EMR documentation of who they communicated with regarding the criteria for Observation Status under Medicare and Manage Medicare. It was emphasized the importance of communicating with the Conservator of Person (COP) if one is identified.• Care Management staff were educated to contact a Patient Access Representative for any patient who has a COP if one is not noted in the ‘Relationship’ section of the EMR.• The Manager of Care Management will emphasize the importance of accurately identifying a patient’s responsible person and/or COP at the upcoming Community Collaborative meeting. The accuracy of the information contained in the Intra-Agency transfer document (W-10) will be stressed as this is critical to the coordination of care.	10/1/2019
<p>Monitoring Plan</p> <ul style="list-style-type: none">• The manager of Care Management or designee will audit 10 records a month for 2 months of Medicare patients admitted to an Observation status to ensure compliance with Observation Notification completion.	7/19/2019
<p>The Director of Patient Access is responsible for the oversight of this section.</p>	7/25/2019
	8/31/2019
	10/1/2019

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7. Based on clinical record review, interview and policy the facility failed to ensure that for one patient (Patient #16) placed in restraints that there was an order for restraints and/or monitoring and/or that the restraints were discontinued at the earliest possible time. The findings include the following:

- a. Patient #16 was admitted to the facility on 12/8/18 at 8:50 PM with hallucinations, paranoid behaviors and a history of alcohol (ETOH) abuse. Review of the record with the Nurse Manager on 12/10/18 at 10:00 AM indicated that the patient arrived to the inpatient unit at 11:35 PM on 12/10/18. The nurse's note dated 12/9/18 at 1:11 AM indicated that the patient arrived from the ED via stretcher with restraints. The patient was noted to be very confused and agitated. The ED record failed to reflect the time of restraint application, behaviors exhibited and/or alternatives attempted. The record failed to reflect an order for restraints, monitoring and/or documentation of the need for the restraint.

Patient #16's record indicated that an order for non-behavioral four point restraints was placed on 12/9/18 at 12:00 AM. A Versed drip was initiated at 12:16 AM. Review of the every 2 hour monitoring indicated that at 6:00 AM on 12/9/18 the identified behavior was subdued, however remained in restraints. The monitoring flow sheet indicated that when reassessed on 12/9/18 at 8:00 AM the behavior identified was subdued and his/her ankle restraints were removed. Although the patient was identified as subdued for the period of 8:00 AM through 4:00 PM on 12/9/18 the patient remained in bilateral wrist restraints on 12/9/18 until 5:52 PM.

Review of the restraint policy indicated that the use of restraints is based on a comprehensive patient assessment that includes a physical assessment to identify medical conditions that may be causing the behavior changes. The restraints are used when the least restrictive interventions have been determined to be ineffective, should be ended at the earliest possible time, and requires an order.

7 DPH Plan of Correction: Restraint Order	Completion Date
• The Emergency Department Leadership will create a competency module on restraint initiation and documentation.	9/30/2019
• Emergency Department Registered Nurses will complete the competency module on restraint initiation and documentation.	10/31/2019
• The Cardiac Care Unit (CCU) Registered Nurses (RNs) will review the Yale New Haven Health System Restraints and Seclusion Policy.	9/1/2019
• The CCU RNs will perform a restraint case review.	9/1/2019
Monitoring Plan	
• The Emergency Department Leadership will audit 10 restraint episodes in the Emergency Department per month for two months to determine compliance with restraint documentation.	12/31/2019
• The Patient Care Manager of CCU or designee will audit ten restraint episodes in CCU, with a focus on the timely removal of restraints, monthly for two months.	11/1/2019

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The Director of Emergency Services is responsible for the implementation and completion of the plan of correction.	
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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1) and/or (i) General (6)

8. Based on clinical record review, interview and policy review the facility failed to ensure44 that for one patient in the ED that the patient's (Patient #24) level of pain was monitored. The findings include the following:

- a. Patient #24 was admitted on 1/21/17 at 8:51 AM after a fall with chest pain. The patient was noted to have multiple rib fractures on the left side with a left moderate hemothorax and a left small pneumothorax. The triage note on 1/21/18 at 9:00 AM indicated that the patient had a pain level of 7/10 after receiving 250 mcg of Fentanyl prior to admission. The record indicated that Dilaudid 1 mg IV push was administered at 9:13 AM, 9:54 AM, 11:06 AM 12:15 PM and 1:55 PM. The clinical record indicated that the patient's level of pain was assessed on 1/21/17 at 10:14 AM as a 9 on a 0-10 scale and an 8 at 10:18 AM. The record failed to reflect that the patient's level of pain had been assessed and/or that the efficacy of the pain medication was reassessed after each dose administered.

Review of the facility policy indicated that pain reassessments are completed to determine whether or not an intervention to ease pain was effective. Reassessment scores are to be recorded in the clinical record.

8 DPH Plan of Correction: ED Level of Pain	Completion Date
<ul style="list-style-type: none">Emergency Department Registered Nurses are undergoing a competency on documentation, which includes a review of the Pain Management policy and the required documentation for it. Pain reassessment is included within this review.	9/30/2019
Monitoring Plan <ul style="list-style-type: none">The Emergency Department Leadership will audit 10 pain reassessments per month for two months to determine compliance with pain reassessment.	12/1/2019
The Director of Emergency Services is responsible for the implementation and completion of the plan of correction.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (4) (A) and/or (d) Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6),

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9. *Based on clinical record review, interview and policy review the facility for 1 of 3 patients who underwent a procedure (Patient #24) the hospital failed to ensure that the integrity of a damaged glove was assessed and/or failed to report an incident to administration. The findings include the following:

- a. Patient #24 was admitted on 1/21/17 at 8:51 AM after a fall with chest pain. The patient was noted to have multiple rib fractures on the left side with a left moderate hemothorax and a left small pneumothorax.

Review of the nurse's notes indicated that a 2:45 PM chest tube was inserted by MD #3. MD #3's note dated 1/21/17 at 4:09 PM indicated that written consent was obtained, the procedure was completed and the chest tube appeared to be in good position and was draining. The record indicated that on 2/3/17 at 12:19 PM MD #3 entered an addendum note. The note indicated that after the trocar was removed from the patient's chest wall and the tube was clamped MD #3 noted a tear in the right index finger of his glove. The note indicated that he removed the glove, no open areas noted, donned a new glove and continued with the procedure. The note indicated that after evaluation of the clinical situation, clinical judgement at the time suggested that there were no significant risk to the patient so the glove tear was not reported.

Interview with MD #3 on 12/12/18 at 1:45 PM indicated that while placing the chest tube an incision was made and he placed his finger at the insertion site and proceeded to introduce the trochar and when removing the trochar noticed that the glove covering his index finger was torn. He removed the glove and applied hand gel to see if there was a stinging sensation indicating a break in skin. MD #3 stated that he never thought the glove had sheared off, he felt like it had just broken and that if it had occurred he would have reported the incident to adverse event reporting system. MD #3 failed to assess the glove after the incident to determine the extent of the tear. Interview with Chief Medical Officer on 12/19/18 at 10:30 AM indicated that he would have expected MD #3 to report the incident at the time it occurred.

9 DPH Plan of Correction: AE Torn Glove	Completion Date
<ul style="list-style-type: none">• The Emergency Room (ER) providers were educated regarding the expectation to examine supplies involved in procedures performed in cavities; and the procedure for reporting suspected or confirmed blood borne exposure or retained foreign body.• The event was shared organizationally as the March Safety Moment and Safety Habit of the month.	3/31/2017
Monitoring Plan <ul style="list-style-type: none">• The ER Quality Director monitored three (3) invasive procedures of the involved provider to ensure the risk for retained foreign body was mitigated. <p>The Department Chair of the ER was responsible for the implementation and completion of the Plan of Correction.</p>	3/31/2017 12/31/2017

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10. *Based on clinical record review, interview and policy review for one patient on 1:1 observation (Patient #1), the facility failed to ensure that an assessment of the patient was completed prior to discontinuing the observation. The findings include the following:

- a. Patient #1 presented to the ED 8/29/18 with hyperglycemia, abdominal pain, nausea and shortness of breath (SOB). The patient had a long history of depression, polysubstance abuse and non-compliance.

Review of the clinical record on 10/31/18 with the Nurse Manager at 9:45 AM indicated that on admission on 8/29/18, Patient #1 denied suicidal ideation, however the note at 9:08 PM indicated that later in the evening the patient stated that he/she felt depressed but denied having a plan (to harm self). A one to one sitter was initiated with a new order to obtain a psychiatric consult. Review of the psychiatric consult (MD #1) dated 8/30/18 indicated that the patient made suicidal statements on admission, the patient was not actively suicidal and the 1:1 sitter was discontinued.

A nurse's note dated 9/2/18 at 9:32 PM indicated that at approximately 8:10 PM Patient #1 was found unresponsive, respirations less than 8, pinpoint pupils and was not arousable to a sternal rub. A rapid response was called and Narcan was administered with positive results. The patient gave staff two wax bags which contained white powder. The 9/3/18 12:37 AM note indicated that the patient admitted to taking an illicit substance given to him/her by a friend and the patient was placed back on 1:1 observation on 9/3/18 at 8:09 AM. The physician's note indicated that the patient was severely depressed with suicidal ideation. An APRN note dated 9/4/18 at 9:08 AM identified that the patient was alert and oriented, awaiting a psychiatric evaluation for inpatient admission and was on a 1:1 for safety. Review of the record indicated that the 1:1 observation status was discontinued on 9/4/18 at 10:09 AM by MD #1.

The clinical record was reviewed with the Nurse Manager on 10/31/18 at 9:45 AM and indicated that the record failed to reflect a documented assessment of Patient #1 by a physician to determine that the patient was appropriate for the discontinuation of the 1:1 observation level.

The record indicated that on 9/5/18 at 10:48 AM Patient #1 was placed on 1:1 observation by the psychiatrist (MD #1).

Interview with MD #1 on 10/31/18 at 2:30 PM indicated that he was notified on 9/4/18 or 9/5/18 of Patient #1's medical incident requiring a rapid response. When MD #1 saw the patient on 9/5/18, the patient was very depressed and requesting inpatient psychiatric treatment. MD #1 indicated that he felt the patient had current suicidal ideation with no plan.

Review of the patient observation policy indicated that discontinuation of a mandatory patient observation requires psychiatry clearance.

10 DPH Plan of Correction: Provider suicide assessment	Completion Date
• Psychiatrists working at L+M will be educated to the <i>Patient Observation and Resource Deployment</i> policy via a read and sign, which includes obtaining a	8/31/2019

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<p>provider order to remove patient observation and that if a patient with a PEC is on observation, only psychiatry can discontinue the observation order.</p> <ul style="list-style-type: none">• Psychiatrists working at L+M will be educated to the new <i>Suicide Risk Screening, Assessment, and Precautions</i> policy via a read and sign; specifically to include the use of an evidenced-based risk assessment. The evidenced based suicide risk assessment determines the risk mitigation strategies and level of observation required.• The Hospitalists group working at L+M will be educated to the <i>Patient Observation and Resource Deployment</i> policy via a read and sign, which includes obtaining a provider order to remove patient observation and that if a patient with a PEC is on observation, only psychiatry can discontinue the observation order.• The Hospitalists group working at L+M will be educated to the new <i>Suicide Risk Screening, Assessment, and Precautions</i> policy via read and sign; specifically to include the use of an evidenced-based risk assessment. The evidenced based suicide risk assessment determines the risk mitigation strategies and level of observation required.	8/31/2019
<p>Monitoring Plan</p> <ul style="list-style-type: none">• The Chairman of the Department of Medicine or his designee will audit 10 records a month, or if less 100%, for 2 months of patients who have had mandatory observation to ensure the proper assessment and order for discontinuation are present in the medical record. Beginning 9/1/19	8/31/2019
<p>The Chairman of the Department of Medicine is responsible for the implementation and completion of the Plan of Correction.</p>	10/31/2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (4) (A) and/or(d) Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6).

11. Based on clinical record review, interview and policy review for one patient (Patient #1) attempting to leave against medical advice (AMA), the facility failed to ensure that the patient was seen/evaluated by a physician, per the facility policy. The findings include the following:

- a. Patient #1 presented to the ED 8/29/18 with hyperglycemia, abdominal pain, nausea and shortness of breath (SOB). The patient had a long history of depression, polysubstance abuse and non-compliance.

Review of the clinical record on 10/31/18 during the period of 9:45 AM through 11:15 AM indicated that on admission to the nursing unit on 8/29/18 the patient denied suicidal ideation, however the note at 9:08 PM indicated that later in the evening the patient stated that he/she felt depressed, denied a plan and that a one to one sitter was initiated with a new order for a psychiatric consult.

The 8/31/18 nurse's note at 11:54 PM indicated that the patient was very anxious and restless at the beginning of the shift and stated that he/she wanted to leave. MD #1 was called and indicated that the patient was not suicidal and could leave if wanted. MD #2 was called and

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stated that the patient could go if he/she wanted. The note indicated that the nurse provided emotional support and the patient stayed. The record failed to reflect that the patient was evaluated.

Review of the facility policy indicated when a patient requests to leave AMA the attending physician should attempt to counsel the patient to stay and have a discussion about the risks of leaving the hospital. If the attending is not available the physicians designee (PA, APRN), Clinical Manager or off shift Supervisor/ Administrator should attempt to counsel the patient.

11 DPH Plan of Correction: AMA assessment	Completion Date
<ul style="list-style-type: none">The Hospitalists group working at L+M will be educated to the <i>Discharge Against Medical Advice</i> policy via read and sign; specifically to include the documentation of having a discussion with the patient about the risks of leaving the hospital and what was done to facilitate the safest discharge. The responsible practitioner will document in the EMR summarizing the events and discussion with the patient regarding the risks of discharge.The Clinical Managers and Assistant Directors of Nursing working at L+M will be educated to the <i>Discharge Against Medical Advice</i> policy via read and sign; specifically to include the documentation of having a discussion with the patient about the risks of leaving the hospital and what was done to facilitate the safest discharge. The responsible practitioner will document in the EMR summarizing the events and discussion with the patient.	8/31/2019
Monitoring Plan <ul style="list-style-type: none">The Chairman of the Department of Medicine or his designee will audit 10 records a month, or if less 100%, for 2 months of patients who have left against medical advice to ensure the documentation of counseling and a safe discharge plan are in the EMR. Beginning 9/1/19	8/31/2019
The Chairman of the Department of Medicine is responsible for the implementation and completion of the Plan of Correction.	10/31/2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6),

12. *Based on clinical record review, interview and policy review the facility failed to ensure for one patient (Patient #6) on a 1:1 that the patient was maintained in a safe manner. The findings include the following:

a. Patient #6 was admitted on 1/21/17 with nausea and vomiting. The H&P indicated that the patient had a history of Diabetes and Sepsis. The patient had been discharged from the hospital 2 days prior to admission secondary to sepsis related to a hip abscess.

The nurse's note dated 1/22/18 at 4:38 PM indicated that the patient was placed on a 1:1 sitter for patient safety and supervision to prevent self-harm. The Infectious Disease

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Consult note dated 1/24/17 indicated that the patient is now on 1:1 observation. The note indicated that there is a strong suspicion of self-inflicted bacteremia and recommended 1:1 for the patient's whole stay. Review of the clinical record failed to reflect an order for the 1:1 observation until 1/26/18. Review of the physician's orders identified an order dated 1/26/18 at 4:18 PM that directed sitter at bedside with the reason identified as self-harm. Review of the facility policy indicated two levels of observation, Patient observer and Maximum Observer however Patient #6's order failed to specify under which category the patient was to be observed.

- b. Review of the psychiatric consult note dated 1/26/17 indicated that the patient had no current suicidal plan, ideation or intent. The patient has full capacity for decision making, recommend tapering of opioids. The nurse's note dated 2/14/17 indicated at 1:44 PM indicated that the patient had an attempted suicide by overdose on 2/13/17 while in the hospital. The record reflected that a rapid response was initiated on 2/13/17 at 12:00 PM when the patient was identified with agonal breathing. The physician note dated 2/13/17 at 2:29 PM indicated that the patient was stating he/she does not want to live and took heroin brought into him/her and that the patient was placed on a Physician's Emergency Certificate (PEC) by psychiatry at that time. The note indicated that the patient has a 1:1 sitter which has been continuous during the present hospitalization.

Interview with RN #8 on 12/19/18 at 1:15 PM indicated that shortly before 12:00 PM she was in the patient's room changing the dressing and informed the patient she would return shortly to obtain a blood sugar. RN #8 indicated that she was called by Sitter #1 that the patient was unresponsive. RN #8 indicated that after the rapid response the patient indicated that he/she "did" heroin through his/her central line. The facility failed to ensure that the patient was monitored to ensure safety.

Review of the Observation policy indicated that the purpose is to provide safe and secure environment for patients. Review of the facility policy indicated two levels of observation, Patient observer and Maximum Observer however Patient #6's order failed to specify under which category the patient was to be observed. The procedure for Maximum observation indicated in part that the patient should be observed at all times, bed linens are not over the head, face and hands are to be observed at all times.

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12 DPH Plan of Correction: Observer	Completion Date
• L+M Hospital adopted the Yale New Haven Health Policy (YNHH): Patient Observation and Resource Deployment.	2/28/2018
• The sitter at bedside order includes a documented reason for the patient observer. The reason for the patient observer determines whether a mandatory patient observer or non-mandatory patient observer is needed.	2/28/2018
• Registered Nurses on Unit 6.2 will be re-educated on the Sitter at Bedside order that contains the reason for the sitter at bedside.	9/1/2019
• Registered Nurses on Unit 6.2 will be re-educated on the YNHHS system policy: Patient Observation and Resource Deployment.	9/1/2019
Monitoring Plan <ul style="list-style-type: none">• The manager of 6.2 or designee will audit 10 sitter at bedside orders on Unit 6.2 monthly for two months to determine if the reason for a sitter at bedside documented within the order aligns with the level of patient observation in place. The Patient Care Manager of 6.2 is responsible for the implementation and completion of the Plan of Correction.	11/1/2019

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2)

13. Based on clinical record review, interview and policy review for 1 of 3 patients (Patient #6) the facility failed to ensure that a comprehensive accurate record was completed for one patient. The findings include the following:

Patient #6 was admitted on 1/21/17 with nausea and vomiting. The H&P indicated that the patient had a history of Diabetes and Sepsis. The patient had been discharged from the hospital 2 days prior to admission secondary to sepsis related to a hip abscess.

The nurse's note dated 1/22/18 at 4:38 PM indicated that the patient was placed on a 1:1 sitter for patient safety and supervision to prevent self-harm. The record reflected that a rapid response was initiated on 2/13/17 at 12:00 PM when the patient was identified with agonal breathing. The physician note dated 2/13/17 at 2:29 PM indicated that the patient was stating he/she does not want to live and took heroin brought into him/her and that the patient was placed on a Physician's Emergency Certificate (PEC) by psychiatry at that time. The note indicated that the patient has a 1:1 sitter which has been continuous during the present hospitalization. The nurse's note dated 2/14/17 indicated at 1:44 PM indicated that the patient had an attempted suicide by overdose on 2/13/17 while in the hospital. Review of the clinical record with the Manager on 12/19/18 at 11:30 AM failed to reflect a nurse's note of what transpired on 2/13/18.

b. The nurse's note dated 1/22/18 at 4:38 PM indicated that the patient was placed on a 1:1 sitter for patient safety and supervision to prevent self-harm. Interview with Sitter #1 on 1/3/18 at 12:15 PM indicated that he began his shift at approximately 11:30 AM on 2/13/17 and at

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that time the patient was sleeping. The sitter indicated that the patient was sleeping the whole time he was in the room and that shortly after he started his shift he went to the computer to enter his documentation and while there the patient was hiccupping and when asked if he/she was alright the patient did not answer, Sitter #1 indicated that the hiccupping occurred a second time and this time he checked the patient and Patient #6 was unresponsive.

Interview with RN #8 on 12/19/18 at 1:15 PM indicated that shortly before 12:00 PM she was in Patient #6's room changing his/her hip dressing and informed the patient she would return shortly to obtain a blood sugar. RN #8 indicated that she was called a short time later by Sitter #1 that the patient was unresponsive.

Review of the Cardiopulmonary resuscitation Record dated 2/13/17 indicated that 12:00 PM an ambu bag was being used to ventilate the patient and that a code was called at 12:05 PM.

Review of the Safety portion of the patient flow sheet completed by Sitter #1 indicated that at 7:55 AM and again at 12:05 PM a "safety round check" was completed, however based on interview and document review the patient was experiencing a medical emergency at that time.

Review of the facility policy indicated two levels of observation, Patient observer and Maximum Observer however Patient #6's order failed to specify which category the patient was under. The policy failed to reflect frequency of documentation

13 DPH Plan of Correction: PEC , Assessment documentation	Completion Date
• Registered Nurses on Unit 6.2 will be educated on the need to ensure Rapid Response events are documented within the EMR.	9/1/2019
• L+M Hospital adopted the YNHH system policy: Patient Observation and Resource Deployment.	2/28/2018
• The sitter at bedside order includes a documented reason for the patient observer. The reason for the patient observer determines whether a mandatory patient observer or non- mandatory patient observer is needed.	2/28/2018
• Registered Nurses on Unit 6.2 will be re-educated on the Sitter at Bedside order containing the reason for the sitter at bedside.	9/1/2019
• Registered Nurses on Unit 6.2 will be re-educated on the YNHH system policy: Patient Observation and Resource Deploy.	9/1/2019
Monitoring Plan	
• The manager of 6.2 or designee will audit ten, or if less than 10 100%, rapid response events per month for two months to determine if the event was documented within the patient's medical record.	11/1/2019
• The manager of 6.2 or designee will audit 10 or all Sitter at Bedside orders on Unit 6.2 monthly for two months to determine if the reason for a sitter at bedside documented within the order aligns with the level of patient observation in place.	11/1/2019

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The Patient Care Manager of 6.2 is responsible for the implementation and completion of the Plan of Correction.	
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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (i) General (6),

14. *Based on document review and interview the facility failed to ensure that suboptimal values obtained during dialysis water testing were addressed.

- a. Review of the Central Reverse Osmosis (RO) log indicated that the water temperature goal was 75-80 degrees. Review of the log for December 2018 indicated that the identified temperatures were 67-73, however the facility documentation failed to reflect that action was taken to correct the issue. Interview with the Biomedical Engineer covering the dialysis unit on 12/12/18 at 11:10 AM indicated that he increased the hot water feed to the mixing valve and the temperatures were currently in range.
- b. The log indicated that the product flow should be 1.0-2.0 however the log indicated that on 12/11/18 the result was 0.8 and on 12/12/18 it was 0.5. The facility documentation failed to reflect that action was taken on the suboptimal level. Interview with the Biomedical Engineer covering the dialysis unit on 12/12/18 at 11:10 AM indicated that he was notified subsequent to surveyor inquiry and he addressed the issue. The Biomedical Engineer indicated that staff should call him if there is a problem.
- c. Review of the portable RO log indicated that the goal pump pressure was 150-200. Review of the log for December 2018 indicated that the documented pump pressures were 118-120, the documentation failed to reflect that biomedical engineering had been notified. Interview with the Biomedical Engineer covering the dialysis unit on 12/12/18 at 11:10 AM indicated that he reviewed the manufacturer's direction for use and subsequently revised the form for the recommended pump pressures of 90-150.

Interview with the Biomedical Engineer covering the dialysis unit on 12/12/18 at 11:10 AM indicated that upon investigation he determined that the some of the information on the forms was outdated or related to previous items of equipment and subsequently revised the forms and reeducated all the staff.

14 DPH Plan of Correction: Dialysis: Central Reverse Osmosis Log.	Completion Date
• Portable Reverse Osmosis (RO) log was assessed for current equipment in use and manufacturer recommendation for pump goal pressure and water temperature.	12/12/2018
• Based on review, the log was revised to align with current equipment and manufacturer recommendations for both pump goal pressure and water temperature goals.	12/12/2018
• Bio-Medical Staff covering the Dialysis Department and Dialysis nurses were re-educated on the log purpose and revisions. This education included the importance of reporting out of specification events and annotating on the log what was done to repair.	12/12/2018
• Education materials for new hire orientation were updated to include the new log and directions for use and reporting of any data out of range.	7/24/2019

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Monitoring Plan	
<ul style="list-style-type: none">The RO log was monitored for 2 months to ensure compliance with manufacturer recommendation for pressure and temperature goal as well as compliance with documentation of any occurrence or repairs. Beginning: 1/1/19	2/28/2019

The Manager of the Dialysis unit was responsible to oversee the completion and monitoring of the plan of correction.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d), Medical Records (2) and/or(e) Nursing Service (1) and/or (i) General (6),

15. Based on clinical record review, interview and policy review the facility failed to ensure that for one patient (Patient #25) with an elevated BP post operatively that the BP was addressed. The finding includes the following:
- Patient #25 presented to the facility on 12/8/18 for a colonoscopy and EGD. On admission the patient had a BP of 121/82. The record indicated that the patient's procedure was completed at 8:24 AM and that vital signs were obtained every 15 minutes. The patients BP was 158/78 at 8:49 AM and 167/ 82 at 9:06 AM. Review of the record with the Nurse Manager on 12/10/18 at 11:00 AM failed to reflect a nurse's note addressing the elevated BP.

15 DPH Plan of Correction: Elevated BP	Completion Date
<ul style="list-style-type: none">Manager of Same Day Surgery (SDS) will provide an educational review of policy: Vital Sign Monitoring Policy to the with Same Day Surgery, Endoscopy, and Recovery Room registered nursing staff.	8/6/2019

The Manager of SDS is responsible to oversee the completion and monitoring of the plan of correction.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e), Nursing Service (1) and/or (i) General (6),

16. *Based on clinical record review, interview and policy review for one of three patients on oxygen (Patient #100) the facility failed to ensure that oxygen was applied by a qualified staff member and/or that the RN followed facility policy. The finding includes the following:
- Patient #100 was admitted to the facility on 4/1/19 with shortness of breath, productive cough and wheezes. The patient has a history of COPD, dependent on Oxygen at home. Review of

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the ED note indicated that the patient had a chest x-ray that indicated congestive heart failure (CHF). The patient was admitted with right middle lobe pneumonia, CHF and COPD exacerbation

Interview with RN #100 on 5/13/19 at 2:30 PM indicated that when Patient #100 returned to the unit she was busy with another patient and that when she checked on the patient she was fine. RN #100 indicated that when she went to set the patient up for lunch the patient appeared to have increased work of breathing and the RN called respiratory for a treatment. RN #100 indicated that the respiratory therapist noted that although the patient had a nasal cannula in place, however it was attached to the air flow meter and not the oxygen flow meter.

Interview with transporter #1 on 5/10/19 at 11:45 AM indicated that on returning the patient to the unit she and Transporter #2 were in the room and prior to transferring the patient from the stretcher to the bed Transporter #2 asked her to hook the patient up to Oxygen and she took the nasal cannula and hooked it to the green Christmas tree adaptor. Transporter #1 indicated that she adjusted the flow rate and once completed left the room and RN #101 was outside the room and signed the ticket to ride for tn.

Interview with the Manager of Support Services on 5/10/19 at 10:00 AM indicated that on 4/8/19 she received communication that on return to the unit transport staff hooked the patient's nasal cannula up to the flow meter. The Manager indicated that on 4/8/19 she posted information on and began having huddles throughout each day to re-educate staff on their role when transporting patients and that unlicensed personnel are not permitted to remove/replace, change over or administer Oxygen.

Interview with the Director of Cardiopulmonary therapies on 5/10/19 at 10:30 AM indicated that all inpatient rooms have piped in oxygen and air. The outlets are color coded (air-yellow, oxygen-green) as are the flow meter. At the time of the incident the nipple on the yellow flow meter was green and that the respiratory therapist found the patient hooked up to a green nipple on a yellow flow meter.

Immediately following the identification of the incident all the air flow meters have been removed from the nursing unit with the exception of the ICU and CCU. If a patient requires the use of air the RT will bring a flow meter with them.

Review of the facility policy "Transport of Patients within the Hospital" indicated that only licensed care practitioners transition patients from Oxygen.

16 DPH Plan of Correction: AE O2	Completion Date
• The transport manager provided education to the transport staff regarding not applying oxygen or transferring oxygen.	5/3/2019 <i>OK per CO</i>
• The nurse manager of the medical-telemetry unit educated the registered nursing staff regarding Ticket to Ride expectations and ensuring proper	5/3/2019

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<p>oxygen settings. This included review of the policy <i>Transport of Patients within the Hospital</i> focusing on review of who can handle and adjust oxygen and the review of the system safety alert titled “Situational awareness regarding oxygen administration”.</p> <ul style="list-style-type: none">• All medical air flowmeters were removed from all patient care areas with the exception of ICU and CCU.• Education regarding removal of all medical air flowmeters and frequency of assessing correct oxygen hook up and flow was provided to Registered Nursing staff. <p>Monitoring Plan</p> <ul style="list-style-type: none">• A question regarding “no airflow meters in patient rooms” was created in our biweekly environment of care survey. This was monitored every two weeks for two months to ensure compliance. Beginning: 4/30/19• The nurse manager of the medical-telemetry unit audited 10 medical records each week for two months to ensure compliance with Ticket to Ride and correct oxygen settings. Beginning: 5/6/19 <p>The Manager of the Telemetry unit was responsible to oversee the completion and monitoring of the plan of correction.</p>	4/18/2019 5/3/2019 6/30/2019 7/6/2019
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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (A) and/or (d) Medical Records (3), and/or (e) Nursing Service (1).

17. Based on clinical record review, interview and policy review for one of three patients (Patient #100) the facility failed to ensure that the patient was assessed after a change of condition and/or that the physician documented an assessment of the patient. The finding includes the following:

- a. Patient #100 was admitted to the facility on 4/1/19 with shortness of breath, productive cough and wheezes. The patient has a history of COPD, dependent on Oxygen at home. Review of the ED note indicated that the patient had a chest x-ray that indicated congestive heart failure (CHF). The patient was admitted with right middle lobe pneumonia, CHF and COPD exacerbation

The nurse's note dated 4/7/19 at 2:23 PM indicated that at 12:30 PM the patient was wheezing and work of breathing noted, respiratory treatment given and the patient was started on BiPap. The note indicated that the patient's oxygen saturations were 95% now and respiratory rate was now 20.

Interview with Transporter #1 on 5/10/19 at 11:45 AM indicated that on 4/7/19 she and Transporter #2 returned the patient to the unit, they were in the room and prior to transferring the patient from the stretcher to the bed Transporter #2 asked her to hook the patient up to Oxygen and she took the nasal cannula and hooked it to the green Christmas tree adaptor Transporter #1 indicated that she adjusted the flow rate and once completed left the room and the RN was outside the room and signed the ticket to ride from.

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Interview with RN #100 on 5/13/19 at 2:30 PM indicated that when Patient #100 returned to the unit she was busy with another patient and RN #101 signed the ticket ride. RN #100 indicated that when she checked on the patient she was fine. RN #100 stated that when she went to set the patient up for lunch the patient appeared to have increased work of breathing and the RN called respiratory for a treatment. The RN stated that she notified the physician however failed to complete vital signs and/or an assessment of the patient, she stated that the physician went to see the patient and instructed her to continue to monitor the patient. Review of the clinical record failed to reflect an assessment of the patient and/or documentation of the incident and/or a note by the physician after the patient had been seen. Review of the Nursing Process policy indicated that a focused reassessment will be completed on all active problems as clinically relevant.

17 DPH Plan of Correction: AE O2 Documentation MD assessment20	Completion Date
• A template for significant event documentation will be developed within the electronic medical record (EMR) for use with the hospitalist group.	7/30/2019
• An SBAR tool will be created and used to educate the hospitalist group on documentation requirements for changes in clinical conditions utilizing the significant event note in the EMR.	8/31/2019
• An SBAR tool will be created and used to educate the 5.4 nursing staff on documentation requirements for any clinically relevant changes in patient conditions. A posttest will be given to all 5.4 nursing staff with an expectation of a grade of 90% or better.	8/31/2019
Monitoring Plan <ul style="list-style-type: none">The chairman of the Department of Medicine or his designee will audit 10 rapid response medical records per month for two months to ensure the significant event template is being used for changes in conditions. Beginning 9/1/19	10/31/2019
The Chairman of the Department of Medicine is responsible for the implementation and completion of the Plan of Correction.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13- (b) Administration (3) and/or (e) Nursing Service (1).

18. Based on review of facility documentation and interview the facility failed to ensure that transportation staff were provided with a comprehensive orientation and/or that documentation of the orientation was available. The findings include the following:
- Interview with transporter #1 on 5/10/19 at 11:45 AM indicated that she and Transporter #2 returned Patient #100 to his/her room on 4/7/19 at 11:33 AM and prior to transferring the patient from the stretcher to the bed, Transporter #2 asked her to hook the patient up to Oxygen and she took the nasal cannula and hooked it to the green Christmas tree adaptor

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Transporter #1 indicated that she adjusted the flow rate and once completed left the room and the RN was outside the room and signed the ticket to ride from.

Interview with the Manager of transportation on 5/10/19 at 12:30 PM indicated that transport staff go through hospital orientation and then are provided with on the job orientation. The Manager indicated that she meets with new staff to discuss their orientation however there is no checklist or formal outline.

18 DPH Plan of Correction: AE O2 Documentation: Patient Transport	Completion Date
• The Manager of Patient Transport provided education to all transportation staff regarding scope of practice which does not include the application of oxygen or transferring oxygen.	5/3/2019
• Sign off by all staff of SBAR System Safety Alert.	5/3/2019
• A collaborative process between Patient transport staff and registered nursing staff was developed that outlines a consistent process for a “hard-stop”: Transport staff do not enter the patient’s room who need O2 connections, without nursing accompaniment.	5/17/2019
• A standardized Patient transport new hire checklist was developed that includes only licensed personnel can handle oxygen and it is not within the scope of the transport staffs role.	8/15/2019
• The Resource Manual utilized by the Transport staff was updated to support the use of the new hire checklist.	8/15/2019
Monitoring Plan <ul style="list-style-type: none">Auditing of all new hires to the transport department will occur for two months to ensure the new hire checklist is completed within two weeks of hire. Beginning 9/1/19	10/31/2019
The Manager of the Transport Department is responsible to oversee the completion and monitoring of the plan of correction.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d)
Medical records (3) and/or (e) Nursing Service (1).

19. Based on a review of clinical records, interview and policy review for one of three patients in the labor and delivery unit (Patient #44) the facility failed to ensure that the clinical record was complete to include physician notification and/or interventions provided to address the patient's low blood pressure. The finding includes the following:
- Patient #44 was admitted on 8/5/16 for a repeat Cesarean section. Review of the operative report dated 8/5/16 identified that the patient had a significant layer of scar tissue at the fascial layer and had bladder flap adhesions. The operative report noted that hemostasis was achieved with an estimated blood loss of 700 milliliters (ml). The patient left the operating room at 9:19 AM and was transferred back to the L&D unit to recover. Review of the clinical record during the period of 9:20 AM-10:49 AM noted the patient was

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hypotensive absent physician notification and/or documented interventions to address the patient's low blood pressures (example; 9:41 AM B/P of 68/45, 10:29 AM B/P 77/40, 10:37 AM B/P 71/30, 10:43 AM B/P 66/34, and 10:49 AM B/P 70/39). Review of MD #15's note dated 8/5/16 at 10:51 AM identified the patient has a post-partum hemorrhage, status post cesarean section, uterus fine in the operating room, and is firm to massage but passing clots intermittently then firms up. Receiving Pitocin intravenously, received three doses of Methergine, and 1 dose of Hemabate (250 mcg), stat hemoglobin 9.7 was 11.2 (normal 11-15 g/dL) preoperatively, B/P now 81/41. MD #15's note at 11:47 AM identified that the patient's bleeding has subsided over the past 45 minutes, pulse 129 and B/P 83/36. Review of the discharge summary dated 8/8/16 identified postpartum hemorrhage secondary to uterine atony and the patient's hemoglobin is 7.9. The patient was discharged home in stable condition.

- b. Review of the clinical record and interview with RN #9 on 2/28/19 at 1:00 PM stated she was the assigned nurse on 8/5/16 and although she had notified MD #15 of the patient's status and interventions were tried, she failed to document this information in the clinical record. Clinical record review and interview with MD #15 on 2/28/19 at 1:30 PM stated he was able to recall standing in the L&D unit making a plan to bring the patient back to the operating room for a bakkri balloon if she didn't get better but could not identify specifically when he was updated and/or notified of the patient's condition.

19 DPH Plan of Correction: AE C-S Bleed	Completion Date
• An educational program "The Importance of Robust Documentation" and a review of the policy on Documentation was provided to the Labor, Delivery and Recovery Postpartum (LDRP) staff by the Quality and Risk Management Specialist.	10/31/2016
Monitoring Plan • The LDRP Patient Safety specialist completed a medical record audit of 10 records per month for 2 months for compliance with documentation of nursing intervention.	12/31/2016
The Manager of LDRP was responsible for the implementation and completion of this Plan of Correction.	

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

20. Based on observation, interview, and policy review, the facility failed to ensure staff thoroughly cleaned the operating rooms in accordance with policy and/or that an effective mechanism to monitor the cleaning of the rooms was documented and/or that a mat utilized on the stretcher was intact. The findings include:

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- a. On 1/31/19 at 9:40 AM, during tour of the Labor and Delivery operating rooms with the Manager the following was observed:
- A medal cart in OR #1 was dusty and contained dusty laminated educational materials.
 - A hover mat on the stretcher had peeling plastic rendering an inability to effectively sanitize the surface between patients.
 - A medal cart in OR #2 was dusty behind the supplies that were stored on the cart. Interview with the Manager stated the rooms were terminally cleaned and should be free from dust and that a new hover mat had been ordered. Interview with the Environmental Services Supervisor on 1/31/19 at 1:02 PM stated terminal cleaning of operating rooms occurs at the end of the day or in unused rooms within 24 hours and although she randomly checks rooms to ensure staff follow policy, these audits are not documented.

Review of the Environmental Cleaning of the Surgical Practice Setting policy directed to wash down all surfaces (tables, mayo stands) between cases and all horizontal surfaces including but not limited to mayo stands at the end of the daily schedule or unused rooms within 24 hours.

20 DPH Plan of Correction: LDRP OR cleaning	Completion Date
• The Environmental Service (EVS) and Labor and Delivery Leadership met and established a new communication process to ensure terminal cleaning in the L&D operating rooms.	2/5/2019
• Verbal education regarding the new communication process and the terminal cleaning of L&D operating rooms was provided to EVS staff who clean the L&D operating rooms.	2/8/2019
• Verbal education on how to document the terminal cleaning of L&D operating rooms was provided to EVS staff who clean the L&D operating rooms.	2/8/2019
• Re-education on the communication process, on terminal cleaning of L&D operating rooms, and documentation of the terminal cleaning of L&D operating rooms will be provided to EVS staff who clean the operating room.	8/9/2019
• Disposable hover mats use has been implemented in the Labor and Delivery Unit.	1/31/2019
Monitoring Plan <ul style="list-style-type: none">• The Surgery Room Cleaning Logs LDRP will be monitored weekly for eight weeks.	10/5/2019
The Director of Environmental Services is responsible for the implementation and completion of this Plan of Correction.	